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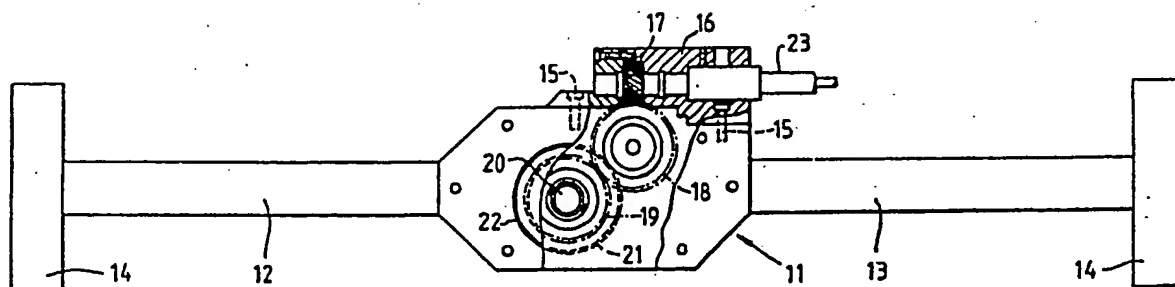
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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<p>(51) International Patent Classification ⁵ : A61B 17/16</p>	<p>A1</p>	<p>(11) International Publication Number: WO 91/03982 (43) International Publication Date: 4 April 1991 (04.04.91)</p>
<p>(21) International Application Number: PCT/GB90/01413 (22) International Filing Date: 13 September 1990 (13.09.90) (30) Priority data: 8920697.3 13 September 1989 (13.09.89) GB (71) Applicant (for all designated States except US): ISIS INNOVATION LIMITED [GB/GB]; 2 South Parks Road, Oxford OX1 3UB (GB). (72) Inventor; and (75) Inventor/Applicant (for US only): BURN, Peter, James [GB/GB]; Nuffield Orthopaedic Centre, Headington, Oxford OX3 7LD (GB). (74) Agent: BOYDELL, John, Christopher; Stevens, Hewlett & Perkins, 5 Quality Court, Chancery Lane, London WC2A 1HZ (GB).</p>		<p>(81) Designated States: AT (European patent), BE (European patent), CH (European patent), DE (European patent)*, DK (European patent), ES (European patent), FR (European patent), GB (European patent), IT (European patent), JP, LU (European patent), NL (European patent), SE (European patent), US. Published With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</p>

(54) Title: APPARATUS AND METHOD FOR ALIGNING DRILLING APPARATUS IN SURGICAL PROCEDURES



(57) Abstract

The apparatus is intended particularly for the accurate drilling of bones preparatory to insertion of cross screws in intramedullary fixation devices. The apparatus comprises a flexible drive (23) whose remote end is connected to a drive motor (not shown). The drive (23) has a gear (17) which in turn rotates gears (18 and 19) mounted in a drill head (11) of radiolucent material. The drill head (11) is equipped with handles (14) whereby the surgeon may control operation of the drill. The gear (18) is made of radiolucent material, but the gear (19) is made of stainless steel, and carries a drill bit (20). A pair of rings (21, 22) coaxial with drill bit (20) and made of radiodense material are attached to the upper and lower surfaces respectively of the drill head (11) so as to be axially spaced. This arrangement enables a parallax method to be used to X-ray align the drill bit. Final accurate alignment may be effected by viewing down the radiolucent interior of the drill bit itself. A two gear version is also described.

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"APPARATUS AND METHOD FOR ALIGNING DRILLING
APPARATUS IN SURGICAL PROCEDURES"

5 This invention relates to drilling apparatus
for use in surgical procedures and, in particular, to
an apparatus and method for aligning such apparatus in
order to assist in the insertion of distal cross-
screws in intramedullary fixation devices. It is to
be understood however that, while the invention is
10 described herein in relation to its use in medicine it
is anticipated that the techniques described will find
wide application in industry wherever accurate place-
ment and alignment of drilling apparatus is necessary.

15 In orthopaedic surgery, damaged bones, partic-
ularly the tibia and femur in the leg, are repaired by
being reamed out axially along their length, and a rod
inserted into the interior of the bone. The rod is
provided with transverse holes into which cross-screws
are screwed to thereby hold the rod firmly within the
20 bone. The transverse holes are normally provided at
opposite ends of the rod so that the broken parts of
the bone are held together in correct alignment,
rotation and length while the bone is healing. The
proximal cross-screw is readily fixed by means of a
25 suitable jig, a technique which is well known and will
not be described. The distal end, however, presents
something of a problem to the surgeon because it is
deeply buried in the bone. The surgeon needs to
drill through the bone at the exact correct position,
30 and in exact alignment with the transverse hole at the
distal end of the rod. Once he has done this, the
cross screw can be inserted and attached as
described. The present invention is primarily,
although not exclusively, concerned with the correct
35 placement and alignment of the drill for the distal
drilling operation.

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US patents 4418422 and 4625718, both assigned to Howmedica International Inc., describe aiming devices for use in osteosynthesis. In both cases, alignment is achieved using an X-ray source and
5 detector rigidly connected together at opposite ends of a C-arm so that the damaged bone can be inserted in the beam path between source and detector. The output from the detector is monitored on a television or similar monitor. The present invention utilises a
10 similar arrangement of X-ray source, detector and display monitor, which will be assumed throughout. US 4625718, in particular, describes an aiming device in which the drill is gripped in the rotating part of an elongate holder having hand grips whereby the
15 surgeon can correctly place and align the drill. The rotating part of the drill is made of a material which is radiolucent - i.e. relatively transparent to X-ray radiation - so that a parallax method can be used to align the drill using the X-ray source-detector
20 arrangement. The drill is rotated by a motor mounted on the holder.

The present invention seeks to provide an improved aiming technique by providing that a fixed (i.e. non-rotating) part of the drill bit holder is
25 made of radiolucent material and is provided with two concentric rings of a radio-opaque material. The rings are spaced apart in the direction of the drill axis whereby, by observing the images of the two rings on the display monitor, the operator can align the
30 drill bit by aligning the rings. It is appreciated that the terms radiolucent and radio-opaque are relative terms; it will be clear that what is necessary is that the concentric rings be relatively more opaque than the surrounding material so that the
35 rings can be readily discerned on the monitor. To allow for accurate placement of the drill tip, it is

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preferred that the drill bit itself, which is usually made from radio-opaque material, is positioned at the centre of the rings and has an axis which is orthogonal to the plane of the two rings. Thus, when
5 viewing the drilling apparatus on the screen, the drill bit will be discernible in the centre of the concentric rings.

The drill bits used can be any of the commercially-available drill bits used in surgical
10 applications; the apparatus can also be adapted to use Kirschner wires. However, in an embodiment of the invention, special drill bits of hollow section are used as a further alignment aid. The drill bits are thus of tubular construction and of radio-opaque
15 material. When seen on the screen, the radiolucent centres of these hollow drill bits appear as a circle when the drill is in exact alignment with the X-ray beam. If out of alignment, the circle is either distorted or, if considerably out of alignment, will
20 disappear altogether. The cutting point of such hollow drill bits may be formed in various ways: for example as a small flat plate of hard material extending diametrically across the drill bit at the end, said plate being shaped to provide a cutting
25 point. With this example, the image of the centre of the drill bit on the screen becomes split in two by the plate, but provided the plate is not too thick in proportion to the interior diameter of the drill bit, the operation is not unduly affected.

30 In a still further alternative, the hollow interior of the drill bit may be plugged at the drill tip end by radiolucent material to aid in cleaning the drill bit. Indeed, the whole interior of the drill bit may be filled with radiolucent material.

35 In a preferred embodiment of the invention the motor for rotating the drill is mounted separately

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from the drive head, and motion is communicated to the drive head by means of a flexible drive. This considerably reduces both the size and the weight of the drive head and makes for an instrument which is much easier to handle and manoeuvre than the known devices. In addition, the flexible drive can be fitted at the remote end to a wide range of available drills, thus increasing versatility, and saving additional costs.

In use, the drill is positioned and aligned by first applying X-ray radiation from the source to the detector through the broken bone. It is assumed that the intramedullary rod is already in place and now needs to be attached at its distal end, and that the limb is clamped in place. The X-ray source-detector arrangement is adjusted so that the X-ray beam is aligned with the transverse hole at the distal end of the rod. This is achieved by watching for a circular image on the screen. The X-ray source-detector arrangement is now clamped in this position. The object of the exercise is to centre the drill bit over the circular image of the transverse hole and, when in this position to align the drill bit with the hole and keep it that way during drilling. This is achieved by viewing the images of the concentric rings on the screen and aligning the images. If the drill bit is hollow (see above) more precise alignment can be obtained by viewing down the hollow interior of the drill bit once the approximate alignment has been obtained using the rings. Preferably the two concentric rings are the same diameter so that alignment is achieved by getting their respective images one on top of the other on the display. The concentric rings may, on the other hand, be of slightly different sizes so that alignment is obtained by visually fitting the image of one within the image

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of the other.

5 The start point for the drilling operation is located, once the X-ray beam has been aligned with the distal hole, by moving the point of the drill bit over the skin of the limb to find the approximate place to make a small, typically 1.5 cm long, incision in the skin through to the bone. For this purpose, the drill bit may conveniently be mounted in a small handle, rather than using the more cumbersome drilling head itself. An example of a suitable handle is described hereinafter.

10 Having exposed the bone, the point of the drill bit is now placed onto the bone surface and moved in order to accurately centre its image with that of the transverse hole in the rod. This will generally be found easier to achieve by slightly tilting the drill bit so that its image on the monitor is arrow-like. Having once located the point of the drill bit over the centre of the transverse hole, the drill bit is then tilted into alignment with the hole by obtaining a concentric image on the monitor and is then twisted back and forth to make a dimple in the cortex. Next, preferably keeping the point located in the dimple, the handle (if fitted) is removed and replaced by the drill head. Alignment of the drill bit is then checked using the concentric rings and hollow drill centre, as described above, and drilling is commenced. The alignment can be checked at intervals during drilling by stopping the rotation of the drill and taking a radiograph.

30 In order that the invention may be better understood, an embodiment thereof will now be described by way of example only and with reference to the accompanying drawings in which:-

35 Figure 1 is a simplified diagrammatic lateral view of the radiographic equipment with which the

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drilling apparatus of the present invention is used;

Figure 2 is a diagrammatic plan view of the drilling apparatus of the present invention;

5 Figure 3 is a plan view, partly in section, and on an enlarged scale, of part of the apparatus of Figure 1.

Figure 4 is a side sectional view of the apparatus of Figure 3;

10 Figure 5 is a diagrammatic side sectional view of a specially-designed hollow drill bit for use with the drilling apparatus of the invention;

Figures 6 and 7 are side sectional and underside plan views respectively of the drill bit shown in Figure 5, on an enlarged scale;

15 Figures 8 and 9 are views similar to Figures 6 and 7 respectively showing an alternative construction of drill bit;

20 Figures 10 and 11 are views similar to Figures 6 and 7 respectively showing a further alternative construction of drill bit;

Figure 12 is a side view, partly in section, of a handle suitable for use in manipulating the drill bit prior to drilling;

25 Figures 13 and 14 are two views of the display screen showing different stages of setting up the drilling apparatus; and

Figures 15 and 16 are views similar to Figures 6 and 7 respectively, showing an alternative embodiment.

30 Referring now in detail to Figure 1 there is shown a simplified view of the radiographic equipment with which the drilling apparatus to be described is used. A limb 1 to be repaired is held in position in the path of an X-ray beam from an X-ray source 3. A
35 detector 4 is mounted in fixed relationship with the X-ray source 3 via a C-shaped arm 5. The detector 4

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receives the X-ray beam and converts it, usually in association with an image intensifier, into an electrical signal which is passed along lead 6 to a television monitor 7. The television monitor is
5 positioned so that it can be viewed by the surgeon and radiographer during the operation to repair the limb.

For the purpose of the present explanation, it is assumed that the bone 8 within limb 1 has already been reamed out in the manner outlined above, and an
10 intramedullary rod 9 fitted. The distal cross hole in the rod 9 is shown under reference 10 in the drawing. The X-ray beam from X-ray source 3 is first aligned with the hole 10 by adjustment of the C-arm 5. The image on the television monitor 7 should now be
15 somewhat as shown in Figure 13. The object is now to drill a hole transversely through the bone 8, which hole is in accurate alignment with the hole 10 in the intramedullary rod so that a screw (not shown) or other equivalent fixation means can be passed through
20 to engage the rod and thereby firmly secure the rod to the bone.

The apparatus for achieving this is illustrated in Figure 2, to which reference will now be made. The apparatus comprises a drill head 11 of
25 radiolucent material, for example polysulfone or acetal, to which are attached two arms 12, 13 which terminate in handles 14. The handles are used by the surgeon to control and operate the drilling apparatus and are well spaced apart so that he can keep his own
30 body well clear of the X-ray beam. Attached at the side of the drill head 11 by means of bolts 15 of radiolucent material is a casing 16 of metal or plastics material, which casing houses the termination of a flexible drive 23 and an associated stainless
35 steel gear 17. The gear 17 drives further gears 18, 19, both mounted for rotation on the drill head 11.

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The gear 18 is of radiolucent material such as delrin; the gear 19 is of stainless steel. Mounted in the centre of gear 19, and for rotation therewith, is a drill bit 20, shown in more detail in Figures 5 to 11 to which reference will shortly be made. The axis of drill bit 20 is orthogonal to the plane of Figure 2.

In use, the remote end (not shown) of the flexible drive 23 is fitted to a standard orthopaedic power drill (also not shown) and rotates the gear 17. Drive is transmitted through gears 18 and 19 to the drill bit 20 which accordingly rotates to carry out the drilling operation. Once the point of the drill bit has been correctly placed, as will be described later, the drill bit is aligned by two methods:

1) by using a hollow drill bit as will be described in more detail later;

2) by obtaining, on the screen of the monitor 7, coincident images of a pair of rings 21, 22 of radiodense material such as stainless steel. The rings 21, 22 are of equal diameter and are both concentric with the gear 19. The ring 21 is mounted in the top surface of drill head 11; the ring 22 (which is not visible in Figure 2) in the bottom surface. The rings do not necessarily need to be mounted exactly as described: in order to parallax the images on the screen, it is only necessary that they be mounted in such a way that they are spaced in the axial direction of the drill bit.

Some additional details of construction will now be described with reference to Figures 3 and 4. The drill head 11 takes the form of a two-part casing of radiolucent material. The two parts 24, 25 of the casing are joined at a dividing line 26 by bolts 27 and are shaped to provide seatings for four bearings 28, two each for the gears 18 and 19. The bearings for gear 18 are preferably of radiolucent material to

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provide a clear radiolucent margin around the rings 21, 22 to aid alignment. Examples of suitable materials are acetal, nylon or Torlon. Similar materials may also be used for the bearings of gear 19, but an option here exists for machined metallic bearings which will perhaps better withstand the axial thrust from the drill bit.

The interior of the casing is hollow to allow the gears 18, 19 to be mounted in the interior. As will be clear from Figure 4, the gear 19 is equipped with a central through-bore in which the drill bit 20 is fitted. Slots 29 are provided in the bore to receive respective lugs 30 forming part of the drill bit - see below. The slots may be shaped, for example bayonet-fashion or spiral to engage more easily, and to allow the drill bit to be securely locked in position when drilling, but readily removable for cleaning and/or replacement.

The casing 16 has a bore 31 in which is fitted the outer (fixed) end of the flexible drive 23. The end is attached by means of a grub screw 32. The inner (rotating) part of the flexible drive terminates in a coupling 33 which transfers the drive to a shaft 34 mounted in bearings 35 and carrying the gear 17.. The bearings 35 need to be strong enough to counter any "toggle" action imparted by the drive shaft. An example would be machined metallic bushes sized to be a press fit in the casing 16. Other types of self-lubricating bearing material may be used with the added security that they will be less prone to radiation damage due to the fact that they are enclosed in the casing 16 which may provide a measure of shielding. The gear 17 is rotatably attached to the shaft 34 by a transverse pin 36.

The construction of the drill bit will now be described in more detail with reference to Figures 6

- 10 -

and 7. The drill bit is essentially in two parts: a wider upper part 37 of stainless steel which locates in the gear 19 and a narrower lower part 38 of stainless steel which carries the cutter itself. The upper part 37 carries the aforementioned lugs 30. Between the upper and lower parts is a stainless steel spacing collar 39 which may be glued in place, or a friction fit, or locked by a grub screw (not shown). The cutter takes the form of a small plate 41 of hard material such as tungsten carbide having V-shaped cutting edges 42. As will be clear from Figure 7, the thickness of the cutter plate 41 is such as to not restrict too greatly the view down the hollow interior of the drill bit, which is necessary when aligning the instrument. It is preferred that the lower part 38 of the drill bit will be replaceable, and there will be made available a selection of different sizes, as required. A typical minimum exterior diameter for the lower part would be 3 mm.

Although not shown, it may be desirable to plug the lower end of the part 38 to assist cleaning. Any such plug should, of course, be made of radiolucent material. Alternatively, the whole of the lower part 38 may be filled with radiolucent material.

Figures 8 to 11 show two further versions of the drill bit. In the embodiment of Figures 8 and 9, the spacing collar is somewhat lengthened, and is made of radiolucent material such as acetal or polysulphone. Other details are the same. In the embodiment of Figures 10 and 11, the wider upper portion 37 takes the form of a thick-walled tube of radiolucent material, for example acetal or polysulphone, into the lower part of which the stainless steel lower part is fitted. Other details are the same.

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In a further embodiment of the invention (not shown), the collar 39 may be replaced by an adaptor to enable commercially-available drills and Kirschner wires to be used. However, unless the adaptor is
5 itself made from radiolucent material this would mean that reliance would have to be placed on the less precise alignment using the parallax rings 21, 22.

Figure 12 illustrates a tool which is used to initially locate the drill bit 20 in preparation for
10 the drilling operation. The tool comprises a T-handle 43 to which is attached a hollow cylindrical section 44 having an interior diameter such as to allow a loose fit with the upper part 37 of the drill bit 20. Diametrically opposite slots 45 are formed
15 in the wall of the section 44 to form a bayonet locking device for lugs 30 on the drill bit. An O-ring 46 of resilient material is provided on the interior wall of section 44 to firmly but resiliently hold the drill bit 20.

Reference is now made to Figures 15 and 16 which illustrate an alternative embodiment of the drilling apparatus using just a single gear, reference
20 47, on the drill head 11. The gear 47 is equipped with a stainless steel insert 48 having formed a central bore in which is pressed a cylindrical
25 stainless steel drive insert 49, the hollow interior of which locates the drill bit 20. Location of the drill bit in this case is by engagement of the lugs 30 in cooperating spiral slots 51 formed in the drive
30 insert 49. The inserts 48 and 49 may be formed integrally as a single unit.

The gear 47 meshes directly with the gear 17 and thus eliminates the need for a third gear. As an
35 example, the gear 17 may be a 50 tooth gear made of delrin and the gear 47 a 100 tooth gear made of delrin with a stainless steel insert 48/49.

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Locating pins 50 extending between the parts 24 and 25 of the casing ensure accurate location of the two parts with respect to one another during assembly. Figure 16 shows a slightly modified drill bit, in which a grub screw 40 is used to replaceably fix the lower part 38 to the upper part 37 via the collar 39. As before, the collar may be of stainless steel, acetal or polysulphone.

The complete sequence of operations in drilling the required hole will now be summarised. After alignment of the distal hole 10 in the intramedullary rod 9 with the X-ray beam emerging from X-ray source 3, the drilling operation is commenced by using the drill bit, conveniently mounted in the handle of Figure 8 providing ease of handling and extra length to keep the hands clear of the X-ray beam, and as a pointer to locate the approximate position on the skin where a short incision is made down to the bone. The point of the drill bit is now moved over the bone until the exact point for drill entry is found by viewing the screen, in the manner described above. A small dimple is now made in the cortex by bringing the drill bit upright and then twisting the drill bit slightly by hand. Keeping the drill point in contact with the dimple, the handle is now removed, and replaced by the drive unit such as that of Figure 2. The surgeon next grips the drive unit by the handles 14 and aligns the drill bit by obtaining on the screen of monitor 7 concentric images of the rings 21, 22. Final adjustment for accuracy can be made by viewing the images of the interior of the hollow drill - any deviation from correct alignment will cause distortion in the circular image of the drill interior on the screen. Serious misalignment will cause the image of the drill centre to disappear altogether. The image of the correctly

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aligned drilling apparatus on the television monitor 7 is illustrated in Figure 14. The image of the correctly aligned drill head 11 as seen on the screen comprises a central circular light portion, representing the hollow drill interior, surrounded by an annular dark portion representing the upper part and collar of the drill bit 20, followed by the gear 19/insert 48 which in turn is surrounded by a generally light area representing those radiolucent parts of the drill head 11, and including gear 18 in the embodiment of Figure 2, immediately surrounding the gear 19/insert 48. In this connection, it will be noted that gear 18, like casing parts 24 and 25 is made of radiolucent material. Exterior from the image of gear 19/insert 48, and within the surrounding light portion are the coincident images of the rings 21/22 represented as a dark ring contrasting with the light image in this area. Thus, it will be seen that the construction of the drill head makes it easy for the surgeon to discern the images of the rings 21/22 and the hollow interior of the drill head for alignment purposes.

Once accurate alignment has been achieved, the drilling operation commences by switching on the motor (not shown) at the remote end of the flexible drive 23. This operation is preferably carried out by another person under the instruction of the surgeon, and when the surgeon is satisfied that alignment is correct. Drive from the motor is transmitted through the flexible drive 23 and, via gears 17, 18 and 19, or 17 and 47, to the drill bit 20. Alignment can be checked from time to time during the drilling operation by stopping the drill and taking further radiographs.

The use of the flexible drive shaft 23 enables the apparatus to be used with any standard drill,

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keeps down the weight of the unit and, in association with handles 14, keeps the operator and the surgeon clear of the X-ray beam. The handles are removable for compactness and to enable them to be sterilised.

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CLAIMS

1. Surgical drilling apparatus comprising a drill head made primarily of radiolucent material, a drill bit mounted for rotation in said drill head, and drive means for rotating said drill bit, said apparatus being characterised in that said drill head carries at least two spaced rings of radiodense material, said rings being coaxial with each other, and arranged so as to enable X-ray alignment of the drill bit by parallax.
2. Surgical drilling apparatus as claimed in claim 1 wherein said drill bit is mounted for rotation with a first gear forming part of said drive means.
3. Surgical drilling apparatus as claimed in claim 2 wherein said first gear is made of radiolucent material.
4. Surgical drilling apparatus as claimed in claim 2 wherein said first gear is made of radiodense material, and is of smaller diameter than said rings.
5. Surgical drilling apparatus as claimed in claim 2 wherein said first gear is made of radiolucent material, but with a central insert of radiodense material carrying said drill bit, and wherein the diameter of said insert is smaller than that of said rings.
6. Surgical drilling apparatus as claimed in any one of the preceding claims wherein said drive means includes a flexible drive for transmitting rotation from a fixed drive source to the drill head.
7. Surgical drilling apparatus as claimed in any one of claims 2 to 5 and claim 6 wherein said flexible drive terminates with a second gear which drives said first gear either directly, or via an intermediate gear.
8. Surgical drilling apparatus as claimed in

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claim 7 wherein said intermediate gear is made of radiolucent material.

5 9. Surgical drilling apparatus as claimed in any one of the preceding claims wherein said rings are of the same diameter.

10. Surgical drilling apparatus as claimed in any one of the preceding claims wherein said rings are positioned so as to be coaxial with said drill bit.

10 11. Surgical drilling apparatus as claimed in any one of the preceding claims wherein said rings are spaced apart in the axial direction of said drill bit.

15 12. Surgical drilling apparatus as claimed in any one of the preceding claims wherein the drill bit is generally tubular, having a hollow interior, with a cutting tip at one end, and engagement means at the other whereby the drill bit is removably attached to the drill head.

20 13. Surgical drilling apparatus as claimed in claim 12 wherein the interior of the drill bit is wholly or partly filled with radiolucent material.

25 14. Surgical drilling apparatus as claimed in either one of claims 12 or 13 wherein at least part of said tubular drill bit comprises a tubular section of radiodense material whereby, when preparing the drill bit for drilling, the radiolucent centre and the radiodense section can be viewed to thereby allow accurate alignment of the drill bit by means of X-rays.

30 15. A method of using the surgical drilling apparatus as claimed in any one of the preceding claims, said method comprising correctly placing the point of the drill bit on a bone to be drilled by viewing of the X-ray image of the drill bit using X-ray alignment apparatus, thence aligning the axis of the drill bit with respect to the X-ray equipment by
35 parallaxing the X-ray images of the two rings, and

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finally energising the drive means to rotate the drill bit to drill the bone.

16. A method as claimed in claim 15 wherein the centre of said drill bit is radiolucent, said method comprising using said parallax method to achieve rough alignment of the drill bit, and thence accurately aligning the drill bit by viewing and adjusting the X-ray image of the radiolucent interior of the drill bit, before commencing the drilling operation.

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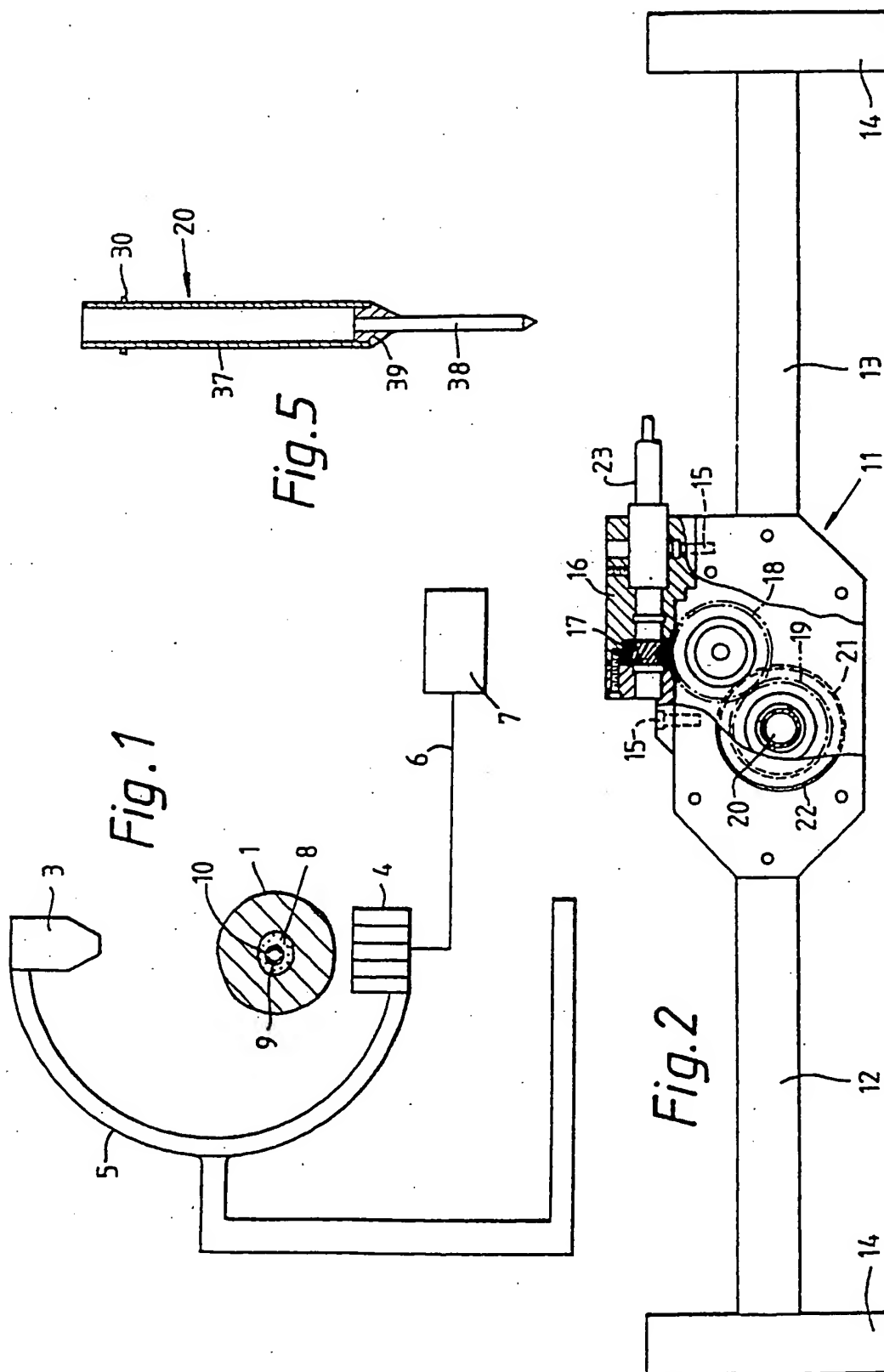
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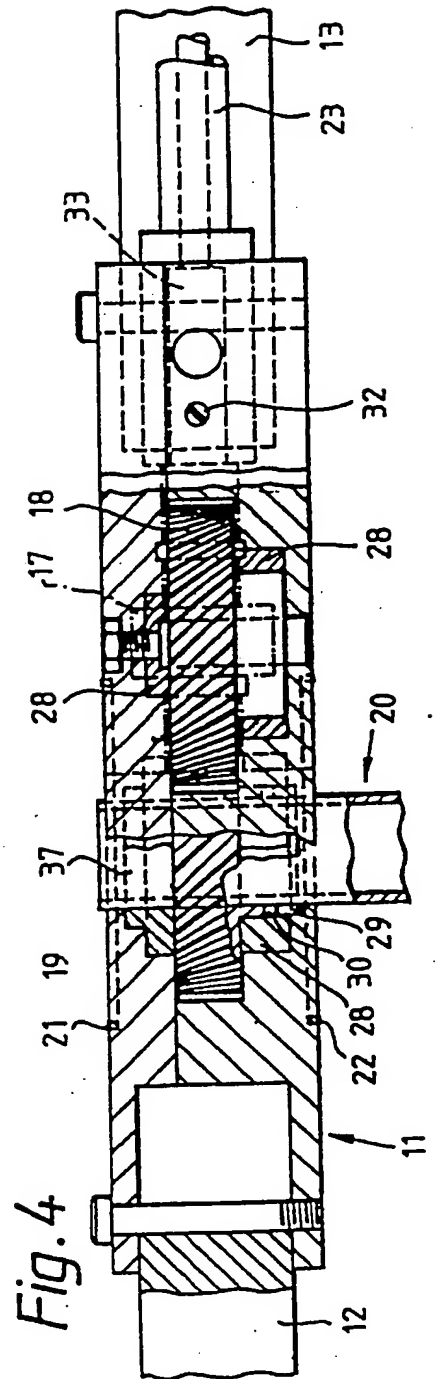
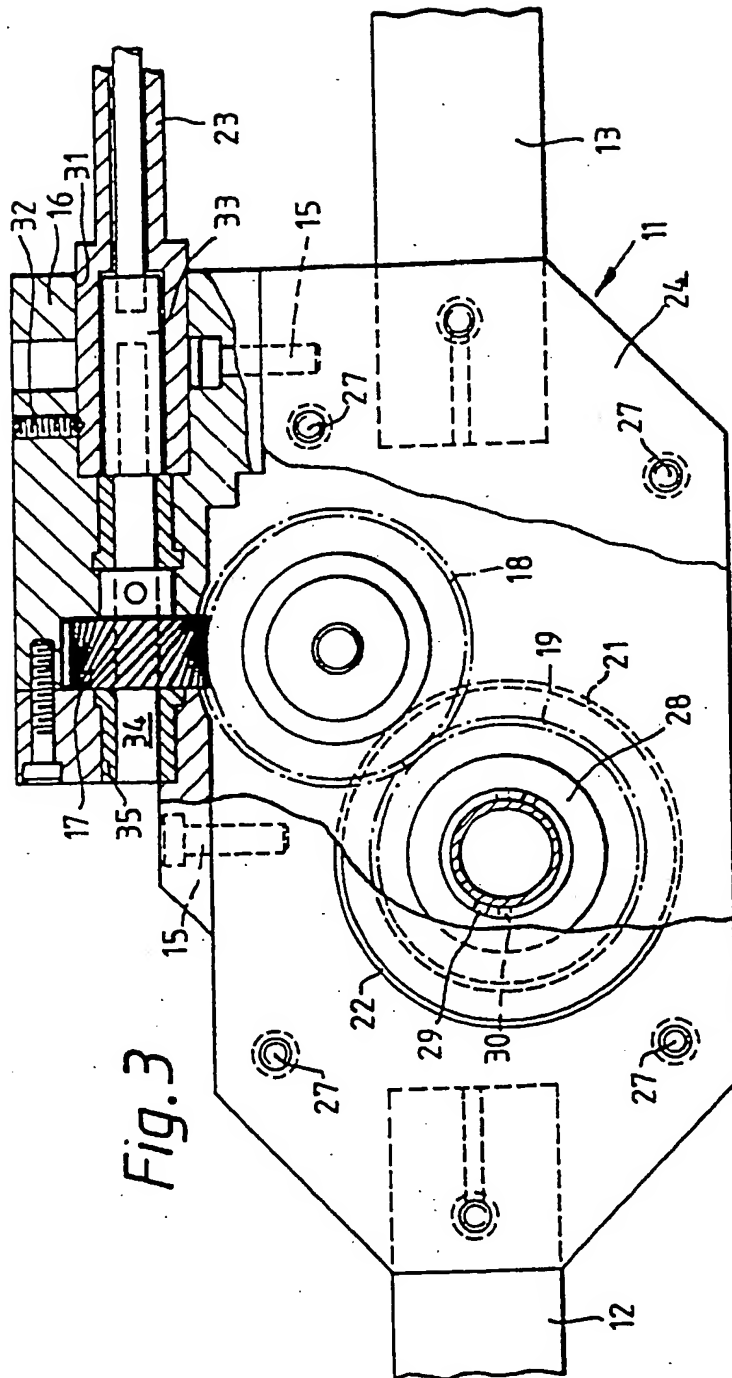
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Fig.6

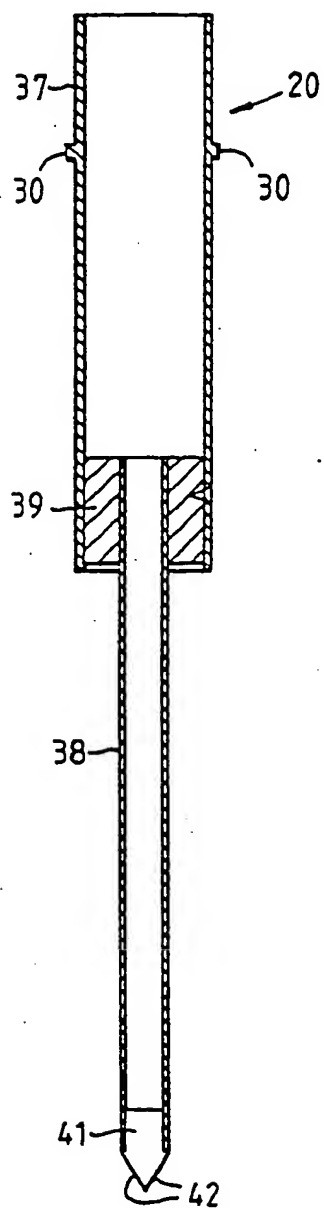


Fig.8

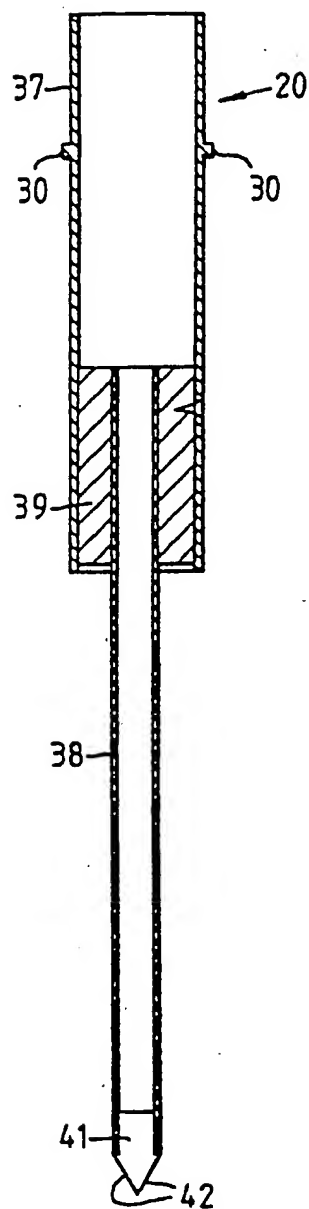


Fig.7

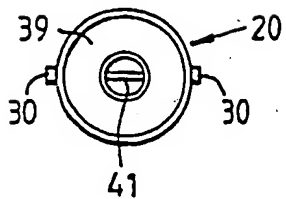


Fig.9

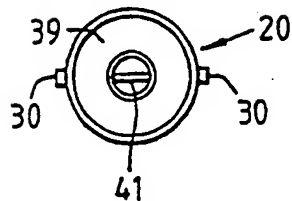


Fig.10

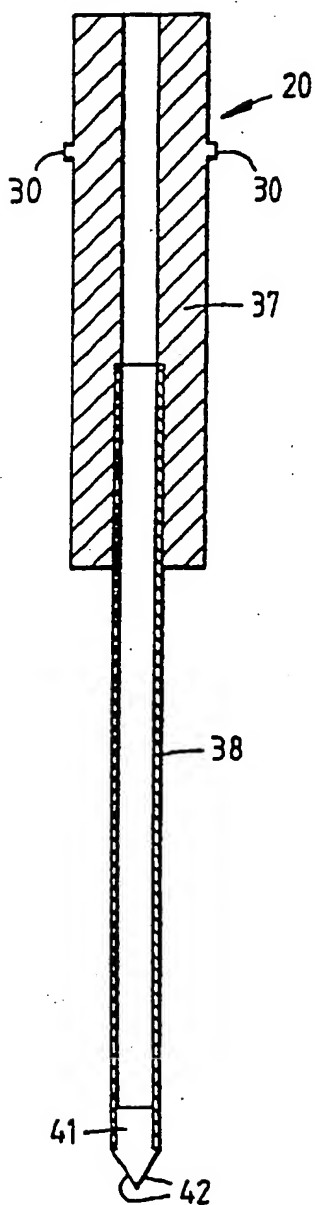


Fig. 11

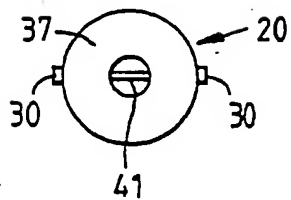


Fig.12

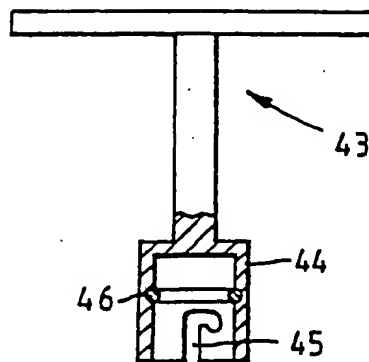


Fig 13

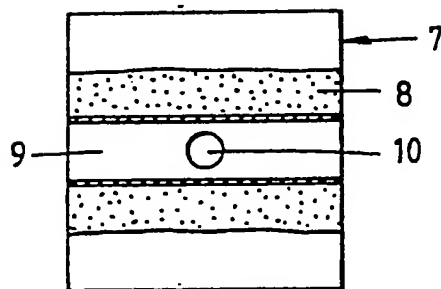
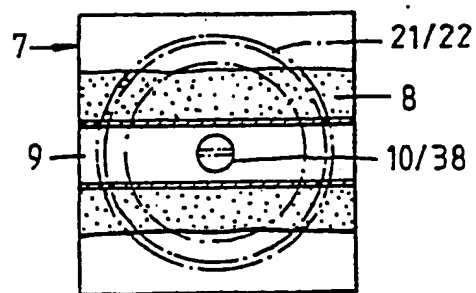
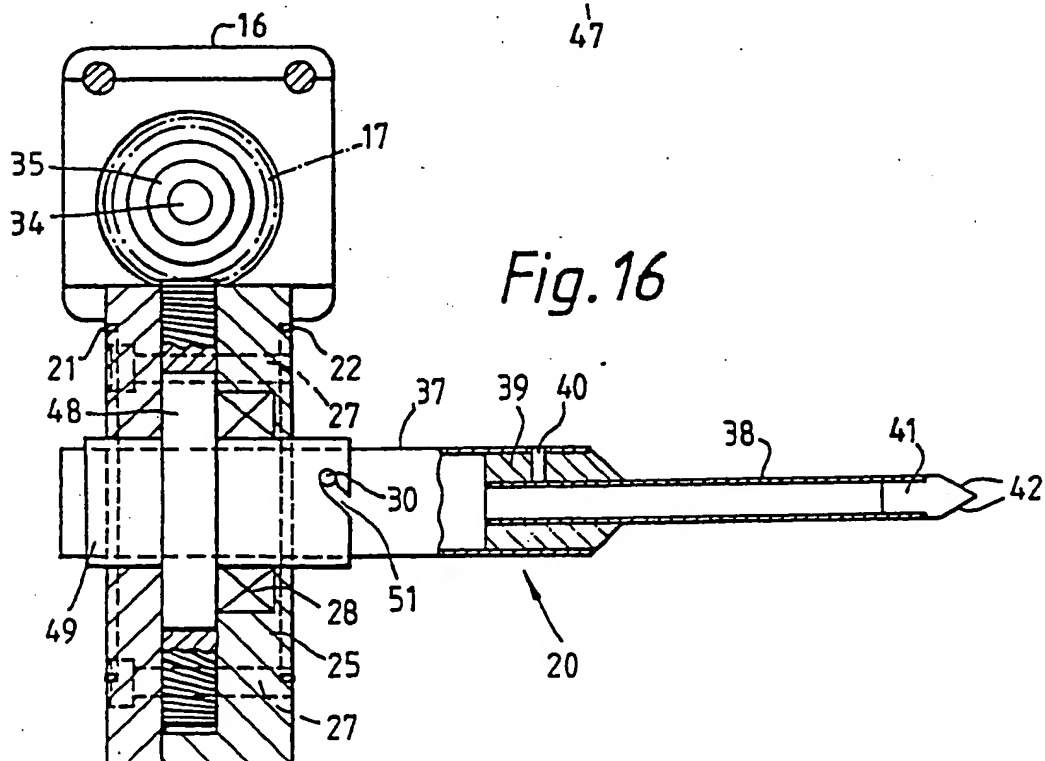
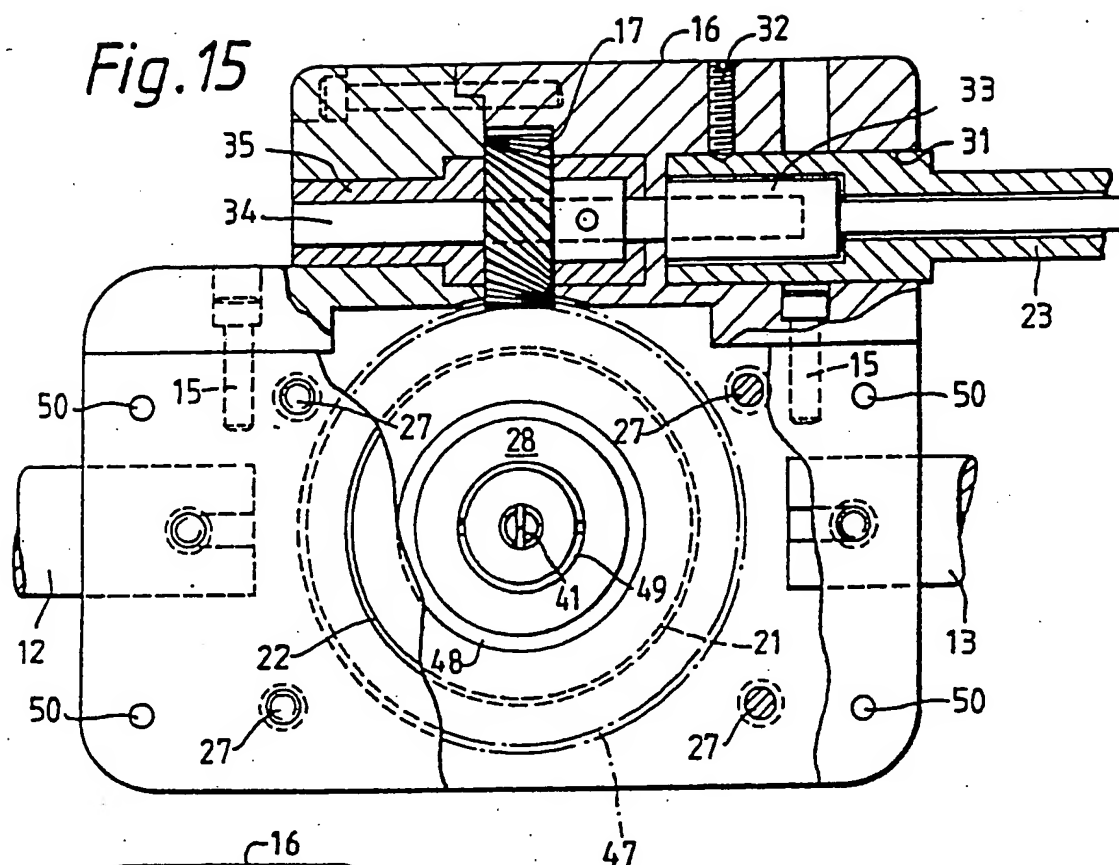


Fig 14








INTERNATIONAL SEARCH REPORT

International Application No

PCT/GB 90/01413

I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all) ⁶ According to International Patent Classification (IPC) or to both National Classification and IPC IPC ⁵ : A 61 B 17/16																				
II. FIELDS SEARCHED <div style="text-align: right; font-size: small;">Minimum Documentation Searched ⁷</div> <table style="width: 100%; border: none;"> <tr> <td style="width: 30%; border: none;">Classification System</td> <td style="border: none;">Classification Symbols</td> </tr> <tr> <td style="border: 1px solid black; padding: 5px;">IPC⁵</td> <td style="border: 1px solid black; padding: 5px;">A 61 B, B 23 Q</td> </tr> </table> <div style="text-align: center; font-size: x-small; margin-top: 5px;">Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁸</div>			Classification System	Classification Symbols	IPC ⁵	A 61 B, B 23 Q														
Classification System	Classification Symbols																			
IPC ⁵	A 61 B, B 23 Q																			
III. DOCUMENTS CONSIDERED TO BE RELEVANT ⁹ <table border="1" style="width: 100%; border-collapse: collapse; font-size: x-small;"> <thead> <tr> <th style="width: 10%;">Category ¹⁰</th> <th style="width: 70%;">Citation of Document, ¹¹ with Indication, where appropriate, of the relevant passages ¹²</th> <th style="width: 20%;">Relevant to Claim No: ¹³</th> </tr> </thead> <tbody> <tr> <td style="text-align: center; vertical-align: top;">Y</td> <td style="vertical-align: top;">EP, A, 0167719 (HOWMEDICA) 15 January 1986 see page 8, lines 8-14; page 9, lines 13-15; claim 1 cited in the application ---</td> <td style="text-align: center; vertical-align: top;">1-16</td> </tr> <tr> <td style="text-align: center; vertical-align: top;">Y</td> <td style="vertical-align: top;">EP, A, 0281763 (HOWMEDICA) 14 September 1988 see column 4, lines 52-54; column 5, lines 27-36 ---</td> <td style="text-align: center; vertical-align: top;">1-16</td> </tr> <tr> <td style="text-align: center; vertical-align: top;">A</td> <td style="vertical-align: top;">DE, A, 3205404 (KLUGER) 15 September 1983 see page 4, lines 17-24 ---</td> <td style="text-align: center; vertical-align: top;">1</td> </tr> <tr> <td style="text-align: center; vertical-align: top;">A</td> <td style="vertical-align: top;">EP, A, 0201737 (FRIGG et al.) 20 November 1986 see claim 1 ---</td> <td style="text-align: center; vertical-align: top;">1</td> </tr> <tr> <td colspan="3" style="text-align: right; padding-right: 10px;">./.</td> </tr> </tbody> </table>			Category ¹⁰	Citation of Document, ¹¹ with Indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No: ¹³	Y	EP, A, 0167719 (HOWMEDICA) 15 January 1986 see page 8, lines 8-14; page 9, lines 13-15; claim 1 cited in the application ---	1-16	Y	EP, A, 0281763 (HOWMEDICA) 14 September 1988 see column 4, lines 52-54; column 5, lines 27-36 ---	1-16	A	DE, A, 3205404 (KLUGER) 15 September 1983 see page 4, lines 17-24 ---	1	A	EP, A, 0201737 (FRIGG et al.) 20 November 1986 see claim 1 ---	1	./.		
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./.																				
<div style="display: flex; justify-content: space-between; font-size: x-small;"> <div style="width: 45%;"> <p>• Special categories of cited documents: ¹⁴</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </div> <div style="width: 50%;"> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"A" document member of the same patent family</p> </div> </div>																				
IV. CERTIFICATION <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border: none;"> Date of the Actual Completion of the International Search <div style="text-align: center;">10th January 1991</div> </td> <td style="width: 50%; border: none;"> Date of Mailing of this International Search Report. <div style="text-align: center;">30. 01. 91</div> </td> </tr> <tr> <td style="border: none;"> International Searching Authority <div style="text-align: center;">EUROPEAN PATENT OFFICE</div> </td> <td style="border: none;"> Signature of Authorized Officer <div style="text-align: center;">  U. TORIBIO </div> </td> </tr> </table>			Date of the Actual Completion of the International Search <div style="text-align: center;">10th January 1991</div>	Date of Mailing of this International Search Report. <div style="text-align: center;">30. 01. 91</div>	International Searching Authority <div style="text-align: center;">EUROPEAN PATENT OFFICE</div>	Signature of Authorized Officer <div style="text-align: center;">  U. TORIBIO </div>														
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III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)		
Category *	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages	Relevant to Claim No.
A	US, A, 4072084 (KNIGHT, Jr., et al.) 7 February 1978 -----	

**ANNEX TO THE INTERNATIONAL SEARCH REPORT
ON INTERNATIONAL PATENT APPLICATION NO.**

GB 9001413
SA 40627

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 21/01/91. The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP-A- 0167719	15-01-86	DE-U- 8417428	13-09-84
		DE-A- 3562178	26-05-88
		JP-A- 60261438	24-12-85
		US-A- 4625718	02-12-86
		US-A- 4850344	25-07-89
EP-A- 0281763	14-09-88	DE-U- 8703438	16-04-87
DE-A- 3205404	15-09-83	None	
EP-A- 0201737	20-11-86	CH-A- 664725	31-03-88
		CH-A- 671873	13-10-89
		JP-A- 62129049	11-06-87
		CA-A- 1271998	24-07-90
		US-A- 4803976	14-02-89
US-A- 4072084	07-02-78	None	